HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Marlin

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

June 23, 1999

Ref: 99-DAL-WL-18

WARNING LETTER

VIA FEDERAL EXPRESS AND
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas B. Marshall
Owner
Delta Catfish Products, Inc.
P.O. Box 99
Eudora, Arkansas 71640

Dear Mr. Marshall:

An inspection of your firm on April 22, 1999, by a Food and Drug Administration, investigator from this office revealed catfish are processed and distributed from your facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented serious deviations from Title 21, Code of Federal Regulations Part 123. These deviations cause your product, catfish, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

As we explained in a previous letter to your firm on July 20, 1998, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at critical control points in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of catfish deviates from the regulations contained 21 CFR Part 123 as follows:

- Failure to have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur (21 CFR 123.6 (b)). Specifically, *Staphylococcus aureus* is not addressed as a potential hazard in IQF battered/breaded catfish fillets and strips.

Additionally, you should have a successfully HACCP trained or qualified individual available to the firm to develop the HACCP plan, reassess the plan and conduct record review in accordance with 21 CFR 123.10. Your firm should maintain sanitation monitoring and control records as required by 21 CFR 123. 11 (c).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA-483 which is a list of the Investigators' observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

Warren L Landry

for Joseph R. Baca
Dallas District Director

JRB:gsg

cc: Mr. Kenny A. Dill, Plant Manager
Delta Catfish Products, Inc.
1424 South Archer Street
Eudora, Arkansas 71640